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08/877, 155 06/17/97 CORMIER

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EXAMINER

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ART UNIT PAPER NUMBER

3763

DATE MAILED: 06/17/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

| | |
|--------------------------------------|--------------------------------------|
| Application No. 08/877,155 | Applicant(s) Cormier et al |
| Examiner Sharon Finkel | Group Art Unit 3763 |

Responsive to communication(s) filed on May 17, 1999.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 6, 7, 30, 31, 53-55, 57-74, and 76-103 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 6, 7, 30, 31, 55, 57, 59-74, 76, 78, and 80-103 is/are rejected.

Claim(s) 53, 54, 58, 77, and 79 is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 6, 7, 30, 31, 55, 57, 59-62, 65, 66, 67, 68, 71-74, 76, 78, 80, 83-86, 89-94, 98-100 are rejected under 35 U.S.C. 102(b) as being anticipated by Ganderton et al., 3,814,097. These claims are directed to generic claims or claims that include the limitation that the anchor may be a projection on a blade or the orientation of the blade. Ganderton discloses a metal sheet punctured with holes. See especially in column 2, lines 8-12. See also Example 5 in column 8. The puncturing inherently results in a conically extending through hole surrounded by an uneven row of triangular shaped projections, each with a different angle orientation. Accordingly, the resulting randomly oriented blades, which must be an inherent product of the puncturing, are seen to anticipate the claimed structure in view of the broad definition of the term "anchor." Regarding the added language that the anchor is further defined as helping to prevent the sheet from being dislodged from the body surface, this broad language is met by Ganderton because the sheet would not be easily dislodged. Further, as defined in the specification, the anchor may be differing angle orientations. Regarding claim 80, the broad definition of the openings in this claim does not preclude the reasonable interpretation that the openings of claim 80 and those defined in claim 30 are the same in structure.

3. Claims 6, 55, 57, 59, 64-66, 71 and 72 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Reed et al., U.S. 5,312,456. The anchor is shown in Figure 13. Regarding applicant's comments, even if the ends of the prong were rounded, the length of the prong extends from the pointed end of the blade upwardly at an approximately a 45 degree angle from the blade.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 63, 64, 69, 70, 81, 82, 87, 88, 95, 96, 97, 101-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganderton et al., U.S. 3,814,097. Regarding claims 63, 64, 81 and 82, Ganderton discloses the claimed subject matter as discussed above except Ganderton discloses 100 *or more* fibers per square centimeter. It is reasonable to interpret that in the case of projections, there may be 100 or more projections as well. Obviously, there is a great difference between the range claimed of 600 to 1000, preferably 800, and the 100 or more disclosed by Ganderton. With regard to claims 69, 70, 87 and 88, it is unclear what the size of the projection might be. Regardless, it appears apparent that this greater number of piercing elements and small size will result in an improved drug delivery device. Accordingly, it is seen as obvious to one of ordinary skill in the art to vary the size and number of the projections depending on the

patient need and the concentration of drug delivered. Regarding claims 97 and 103, clearly the degree of percolation, as well as the blade choice, is also a obvious to one of ordinary skill in the art depending on the patient need and the concentration of drug delivered. See also MPEP 2144.04, IV., A., which supports the Examiner's *prima facie* obviousness rejection.

6. Claims 7, 63, 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 5,312,456. Reed fails to disclose the number of blades per square centimeter and the size of the blades. Regardless, it appears apparent that increasing numbers and decreasing sizes of blades, or visa versa, will result in an alternate drug delivery device which will deliver drugs at different rates. Accordingly, it is seen as obvious to one of ordinary skill in the art to vary the size and number of the projections depending on the patient need and the concentration of drug delivered. See also MPEP 2144.04, IV., A., which supports the Examiner's *prima facie* obviousness rejection. Regarding claim 7, it is obvious to one or ordinary skill in the art to deliver the type of drug necessary according to the patient's need.

Allowable Subject Matter

7. Claims 53, 54, 58, 77, 79 would be allowable if rewritten to include all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: Regarding claims 53, 54, the prior art does not disclose or suggest an anchor in the form of adhesive on a surface of at least one of a plurality of blades. In addition, none of the prior art discloses or suggests an anchor which is a *prong* in combination with the agent delivery or

sampling device. Applicant's arguments with the respect to the unobviousness of a combination the features of, for example, the Latterel '110 anchors and, for example, the embodiments of Gerstel et al. '482 are noted and agreed with. Regarding claim 79, none of the prior art shows or remotely suggests this feature. Note that claim 30 and dependent claims therefrom have not been rejected in view of Reed et al., U.S. 5,312,456. Clearly, Reed does not disclose or suggest a plurality of blades located along a periphery of one opening. Regarding claim 58 in view of Reed et al., US '272, clearly there is no motivation to alter the barbs 72 so that it has only one projecting extremity portion 26, particularly in view of the discussion concerning Figure 1 of the Reed et al. patent.

Response to Arguments

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. Regarding Ganderton et al., applicant should note that the method of puncturing is set forth in column 8, lines 53+. Note that the diameter of the hole produced is less than the length of the burr, suggesting a stretching of the medal to a breaking point, which would inherently yield very sharp edges.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Finkel whose telephone number is (703) 305-0154.



Sharon Finkel

June 14, 1999